REMARKS

Claims 22-57 presently appear in this case. No claims have been allowed. The official action of August 3, 2006, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating a viral infection by the administration of interferon via oromucosal contact. The dose is a high dose which is greater than 20 x 10^6 IU of interferon for a 70 kg human, preferably greater than 30 x 10^6 IU of interferon, which dose is in excess of a dose of the same interferon which induces a pathological response when parenterally administered.

Claims 22-57 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The examiner pointed out a number of places where there is lack of antecedent basis or where the word "about" is objected to.

All of the claims have now been amended in order to address each of the points raised by the examiner and to insert appropriate antecedent basis and to remove the term "about" which the examiner considers to be indefinite. Accordingly, it is submitted that, as amended, the present claims obviate this rejection. Reconsideration and withdrawal thereof is therefore respectfully urged.

Claims 22-32, 36-52 and 56-57 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 3-15 of U.S. Patent No. 6,207,145 and claims 1-14 and 16 of U.S. Patent No. 5,997,858. The examiner states that the present claims are not patentably distinct from the claims of the '145 and '858 patents because the methods for treating a neoplastic condition in the previous patents render the instant methods obvious when the method is used to treat a neoplastic condition caused by a virus. The examiner refers to the disclosure in the '145 patent and the '858 patent in order to support the obviousness rejection. This rejection is respectfully traversed.

First, it is urged that it is totally improper for the examiner to use any of the disclosure from the '145 and '858 patents in order to support the double patenting rejection, as double patenting is based on the claims of the patent and not to the disclosure. The disclosure is not prior art. The claims of the '145 and '858 patents say nothing about oromucosal administration of interferon being used to induce antiviral, antiproliferative and other immunomodulatory effects, and the claims say nothing about the effectiveness of oromucosal interferon against vesicular stomatitis virus. When determining whether the present claims would be obvious

from the claims of the previous patents, which patents are not available as prior art, one must consider only the claims in light of any other reference that is available as prior art.

Note to MPEP §804 II.B.1, where it states:

> When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.

The specification can be used as a dictionary to learn the meaning of a term in the patent claim, but only that part of the patent which pertains to the invention claimed in the patent may be considered as it is only this portion of the specification that supports the patent claims. Thus, anything in the '145 and '858 patents relating to anti-viral activity is not a portion of the specification that supports the anti-neoplastic claims and cannot be used by the examiner in his obviousness analysis.

While it is possible for a tumor to be of viral etiology, the examiner has cited no prior art to establish why one of ordinary skill in the art would consider that the treatment of viral infections of the present claims would have been obvious from claims directed to the treatment of neoplastic conditions. Regardless of its etiology, a tumor is very different from a virus and one of ordinary skill in the art would have no reason to believe that a drug useful for

treatment of a tumor would be expected to be useful for treatment of a virus. Furthermore, there is no reason to believe that the virus that was the originating cause of the tumor would still exist in the patient when the tumor has developed enough to be diagnosed and treated. The examiner has not established a *prima facie* case that this might happen. Even if it did, there is no reason to believe that such a virus could be treated with oromucosally administered interferon, knowing only that that interferon may only be used to treat the neoplasm.

Notwithstanding all of the above, an obviousness-type double patenting rejection with respect to the '145 patent is precluded by 35 U.S.C. 121. The third sentence of 35 U.S.C. 121 states:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

In the prosecution of the application that issued as the ‘145 patent, a restriction requirement was issued on January 20, 1998, in which group II included “claims 6 and 13 drawn to

treating neoplastic condition" and group III was "claim 7 drawn to treating viral infection." The present application is a divisional filed before the issuance of the '145 patent, drawn to the non-elected invention of treating viral infection. Accordingly, a double patenting rejection is prohibited, see MPEP 804.01. Reconsideration and withdrawal of the double patenting rejection, at least insofar as the '145 patent is concerned, is required.

It should further be noted that the '858 patent claims low dose administration of interferon, while the present claims are directed to high dose administration of interferon. The present claims require greater than 20 X 10^6 IU of interferon for a 70 kg human being, whereas the claims of the '858 patent require less than that amount. This is another reason why the present claims would not have been obvious from any reading of the claims of the '858 patent. Furthermore, if a double patenting rejection cannot be made with respect to the '145 patent, it makes no sense to make one with respect to the '858 patent. For all of these reasons, reconsideration and withdrawal of the double patenting rejection are respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and

fully comply with 35 U.S.C. 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /rlb/
Roger L. Browdy
Registration No. 25,618

:rd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\P\phaq\Tovey1A\Pto\2006-11-03AmdL.doc